ETHYLENEAMINES PRODUCT STEWARDSHIP DISCUSSION GROUP
AEEA TESTING CONSORTIUM

8EHQ-1103-15167

October 28, 2003

Via Certified Mail
Return Receipt Number 7001 2510 0002 3427 7333

TSCA Section 8(e) Coordinator
Document Control Officer (MC-7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Contain No CBI

Re: Toxic Substances Control Act -- Section 8(e)

Dear TSCA Section 8(e) Coordinator:

The Ethyleneamines Product Stewardship Discussion Group (EPSDG) Aminoethylethanolamine (AEEA) Testing Consortium, c/o Mr. William C. Hayes, The Dow Chemical Company, 1691 N. Swede Road, Midland, Michigan 48674, submits to the U.S. Environmental Protection Agency (EPA), pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), interim results of a histopathology processing and examination study with AEEA (CAS No. 111-41-1). On July 3, 2002, the EPSDG submitted a notice pursuant to TSCA Section 8(e) for an Organization for Economic Cooperation and Development (OECD) 421 Reproduction/Developmental Toxicity Screening Test in Wistar rats (strain CrlGlxBrlHan:WI) with AEEA. The histopathology study that is the subject of this notice is a follow-up study to the OECD 421 study.

The Dow Chemical Company • Mr. William C. Hayes • 1691 N. Swede Road • Midland, Michigan 48674
Huntsman Ethyleneamines, Ltd. • Mr. Michael O. Nutt • 7114 North Lamar Boulevard • Austin, Texas 78752
Akzo Nobel Functional Chemicals LLC • Mr. Mark R. Schroeder • 5 Livingstone Ave • Dobbs Ferry, NY 10522
BASF Corporation • Ms. Patricia A. Cruse • 3000 Continental Drive • Mt. Olive, New Jersey 07828
BASF Agktingesellschaft • Roland Rossbacher, Ph.D. • Carl-Bosch-Strasse 38 • Ludwigshafen • Rheinland-Pfalz, D-67056, Germany

MR 270715

The EPSDG AEEA Testing Consortium is comprised of the following companies: Akzo-Nobel Functional Chemicals, LLC, BASF Corporation, The Dow Chemical Company, and Huntsman Corporation.[1] The study was performed by BASF Aktiengesellschaft, Ludwigshafen, Germany.

This information is being submitted, as required under TSCA Section 8(e), within 30 calendar days after the date this information was obtained. A summary describing the nature of the adverse effects being reported is discussed below. The initial findings observed are the same as were reported for the OECD 421 study, however, the length of dosing is materially different for the histopathology study.

- **Methods**: The study was carried out to gather information on the optimal histopathologic processing and examination of the malformations of the major pericardial blood vessels as observed in an earlier conducted OECD 421 study. There are no guidelines for this special study. The test substance was administered as an aqueous solution by oral gavage to nine presumed pregnant female rats per group at doses of 0 and 50 mg/kg-bw. Within each group, a subgroup of 3 females was dosed on gestation day 6 through gestation day 20, from gestation day 6 to day 4 post-delivery, and from gestation day 6 to day 21 post-delivery. Developmental toxicity was assessed through a macroscopic examination of gestation day 20 fetuses, post-delivery day 4 pups, as well as post-delivery day 28 pups, with particular attention being paid on the major pericardial blood vessels. All fetuses and pups were preserved for possible histopathologic processing and examination.

- **Results**: No clinical observations were noted in the dams, nor were there any macroscopic findings in the fetuses on gestation day 20. Three out of 24 test substance treated post-delivery day 4 pups showed alterations of the major pericardial blood vessels, such as aneurysms or dilations of aortic arch. Four out of 24 test substance treated post-delivery day 28 pups still showed alterations of the major pericardial blood vessels, such as slight dilations of aorta and/or aortic arch. No mortalities have occurred in the pups being raised until post-delivery day 28. Histopathologic processing and assessment is ongoing.

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[1] We note that although the July 3, 2002, TSCA Section 8(e) letter was submitted on behalf of the EPSDG, this letter is submitted on behalf of the EPSDG AEEA Testing Consortium, a consortium of EPSDG members that are AEEA producers.

Any subsequent information regarding the developmental toxicity of this chemical from this study that is considered to present a substantial risk to human health or the environment under TSCA Section 8(e) will be submitted to the Agency.

If you have any questions, please contact Lynn Bergeson at (202) 557-3801 or lbergeson@lawbc.com.

Sincerely,

/s/

William C. Hayes, Chair
Ethyleneamines Product Stewardship
Discussion Group AEEA Testing Consortium

cc: Ethyleneamines Product Stewardship Discussion Group AEEA Testing Consortium (via e-mail)